Application Serial No. 10/780,904
Response to Official Action of September 3, 2004
Dated: December 3, 2004

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1-14 (canceled)

15. (original) An anti-FSH monoclonal antibody as expressed by hybridoma cell line ECACC 00034004.

16. (original) An anti-FSH monoclonal antibody as expressed by hybridoma cell line ECACC 00034005.

17. (canceled)

18. (previously presented) A method for testing a human female individual to determine if the human female individual is pre-menopausal or post-menopausal, comprising the steps of:

(a) obtaining a gonadotropin-containing sample from the human female individual, wherein the gonadotropin present in the sample exists in a plurality of different forms, and wherein the form or forms in which the gonadotropin exists differ depending on whether or not the human female individual is pre-menopausal or post-menopausal;

(b) performing contemporaneous first and second assays on the sample obtained in step (a),

said first assay producing an indication of the gonadotropin that is independent of the whether the individual is pre-menopausal or post-menopausal,

and said second assay producing an indication of the gonadotropin, wherein the indication produced in the second assay when the human female individual is pre-menopausal is different from the indication produced in the second assay when the human female individual is post-menopausal, and

(c) comparing the results of the first and second assays to determine the human female individual is pre-menopausal or post-menopausal.

19. (previously presented) The method of claim 18, wherein the gonadotropin is follicle stimulating hormone (FSH).

20. (previously presented) The method of claim 19, wherein the first and second assays are sandwich-format assays.

21. (currently amended) The method of claim 20, wherein the first assay makes use of a first antibody pair directed against the combined alpha and beta ~~peptide~~ chains of FSH, and the second assay makes use of a second antibody pair directed against the combined alpha and beta ~~peptide~~ chains of FSH, and wherein both members of the first antibody pair are different from the members of the second antibody pair.

22. (previously presented) The method of claim 21, wherein the first antibody pair detects total FSH.

23. (previously presented) The method of claim 21, wherein the first and second assays each provide a quantitative result, and the ratio of the two results is determined as an indication of menopausal status.

24. (currently amended) The method of claim 21, further comprising the step of obtaining a second sample from the individual after an interval of at least one week and performing a repeat set of ~~repeating the two~~ contemporaneous first and second assays on the second sample ~~after an interval of at least one week~~ to determine if the menopausal status of the human female individual is changing.

25. (previously presented) The method of claim 24, wherein the human female individual is one undergoing a course of hormone replacement therapy.

26. (previously presented) The method of claim 18, wherein the first and second assays are sandwich-format assays.

27. (previously presented) The method of claim 26, wherein the first assay makes use of a first antibody pair directed against the alpha and beta peptide chains of the gonadotropin, and the second assay makes use of a second antibody pair directed against the alpha and beta peptide chains of the gonadotropin, and wherein both members of the first antibody pair are different from the members of the second antibody pair.

28. (previously presented) The method of claim 27, wherein the first and second assays each provide a quantitative result, and the ratio of the two results is determined as an indication of menopausal status.

29. (previously presented) The method of claim 28, further comprising the step of obtaining a second sample from the individual after an interval of at least one week and performing a repeat set of ~~repeating the two~~ contemporaneous first and second assays on the second sample ~~after an interval of at least one week~~ to determine if the menopausal status of the human female individual is changing.

30. (previously presented) The method of claim 29, wherein the human female individual is one undergoing a course of hormone replacement therapy.

31. (currently amended) ~~The method of claim 18~~, wherein the first and second assays are configured such that the such that when the human female individual is in a pre-menopausal state both assays give rise to a similar indication, and when the human female individual is in a post-menopausal state the indication from the second assay is discernably different from the indication of the first assay.

32. (previously presented) The method of claim 31, wherein the indications produced by the first and second assays are the formation of color.

33. (currently amended) An assay device for determination of whether a human female individual is pre-menopausal or post-menopausal by testing of a sample of body fluid, comprising:

(a) a first gonadotropin-responsive signal producing means that, relative to a reference standard, produces a signal indicative of the gonadotropin present in the sample that is independent of ~~the~~ whether the human female individual is pre-menopausal or post-menopausal ;

(b) a second gonadotropin-responsive signal producing means that, relative to a reference standard, produces a signal indicative of the gonadotropin present in the sample that is different depending on ~~the~~ whether the human female individual is pre-menopausal or post-menopausal; and

(c) means for combining the signals produced by the first and second gonadotropin-responsive signal producing means to provide a determination of whether the human female individual is pre-menopausal or post-menopausal.

34. (previously presented) The assay device of claim 33, wherein the first and second gonadotropin-responsive signal producing means produce signals indicative of follicle stimulating hormone (FSH).

35. (previously presented) The assay device of claim 34, wherein the first and second gonadotropin-responsive signal producing means each produce a signal as a result of binding in a detection zone of a labeled specific binding reagent with a particulate direct label.

36. (previously presented) The assay device of claim 35, wherein said labeled specific binding reagent is an antibody directed against the alpha or beta peptide chains of FSH.

37. (previously presented) The assay device of claim 33, wherein the first and second gonadotropin-responsive signal producing means each produce a signal as a result of binding in a detection zone of a labeled specific binding reagent with a particulate direct label.